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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,651	07/09/2003	Pu Zhou	1001.1662101	9310

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EXAMINER

BECK, DAVID THOMAS

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,651

Applicant(s)

ZHOU, PU

Examiner

David T. Beck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because the abstract does not include the steps for the process. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 3, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (3,485,234).

With regard to claim 1, Stevens teaches a method of forming a catheter (abstract), comprising: providing a braid layer having a distal end and a proximal end (column 2, lines 5-10); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (column 2, lines 5-10, first polymer segment covers entire braid layer including proximal end); cutting through the braid layer at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (column 2, lines 14-15); and securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position (column 2, lines 22-33).

With regard to claim 3, Stevens teaches that securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (column 2, lines 29-33).

With regard to claim 11, Stevens teaches that the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip (column 3, lines 22-29; Figure 3).

With regard to claim 13, Stevens teaches providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the

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cutting position (column 2, lines 14-15, cutting a run of body material includes separating two whole catheters which would make the braid layer extend a distance equal to the entire catheter body or more beyond the cutting position).

5. Claim 1, is rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (EP 0,841,072 A2).

With regard to claim 1, Stevens teaches a method of forming a catheter (abstract), comprising: providing a braid layer having a distal end and a proximal end (column 6, lines 47-49); securing a first polymer segment over the braid layer (column 6, lines 50-54), the first polymer segment being positioned proximal of the distal end of the braid layer (figure 2c, numbers 14, 16 and 18), the first polymer segment having a distal end and a proximal end; cutting through the braid layer at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (column 6, lines 54-58; column 7, lines 1-7); and securing a second polymer segment over the braid layer (column 7, lines 7-12), the second polymer segment extending over the first polymer segment and extending distally of the cutting position (Figure 2e, number 36).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-5, 7 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (EP 0,841,072 A2) in view of Wilson (5,951,929).

With regard to claim 2, Stevens teaches the invention of claim 1 as discussed above, but does not expressly teach that the first polymer segment has a melting point that is at least about 10°F above a melting point of the second polymer segment. Wilson teaches using a blend of PEBA and approximately 30% BASO₄ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). Thus, Wilson teaches that the first polymer segment has a melting point that is at least 10°F (25°F) above the melting point of the second polymer segment. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use ARNITEL™ as the first polymer segment as taught by Wilson in the process taught by Stevens. The motivation to do so would have been to more effectively hold the ends of the wire in place by using a first polymer segment that does not remelt (Wilson, column 9, lines 41-50).

With regard to claim 3, Wilson teaches securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (column 9, lines 27-35).

With regard to claim 4, Wilson teaches positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer segment but not enough heat to melt the first polymer segment (column 9, lines 21-50).

With regard to claim 5, Wilson teaches that the first polymer segment has a melting point that is greater than about 400°F and the second polymer segment has a melting point that is less than about 400°F. Wilson teaches using a blend of PEBA and approximately 30% BASO₄ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36).

With regard to claim 7, Wilson teaches the first polymer segment comprises a polyether-ester elastomer (column 9, lines 20-25).

With regard to claim 9, Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54).

With regard to claim 10, Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54).

With regard to claim 11, Wilson teaches the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip (column 8, lines 50-65).

With regard to claim 12, Wilson teaches providing an inner lubricious liner positioned within the braid layer (column 7, lines 21-25), and the cutting through the braid layer further taught by Stevens would necessarily comprise cutting the inner lubricious liner when the catheters are finally separated (column 10, lines 32-34).

With regard to claim 13, Stevens teaches providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at

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the cutting position (column 10, lines 32-34, the final cutting includes separating two or more whole catheters which would make the braid layer extend a distance equal to the entire catheter body or more beyond the cutting position).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (EP 0,841,072 A2) in view of Wilson (5,951,929) and Zadno-Azizi (US 2004/0015150).

With regard to claim 6, Stevens in view of Wilson teaches the invention of claim 4 as discussed above, but fails to explicitly teach that the second polymer segment has a melting point that is about 350°F. Zadno-Azizi teaches a catheter outer coating (Pebax) that has a melting point at about 350°F (paragraph 0177). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Pebax as the outer coating of the catheter produced by the method taught by Stevens in view of Wilson. The motivation to do so would have been to create a flexible elongate tubular member from a suitable material (Zadno-Azizi, paragraph 0175).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (EP 0,841,072 A2) in view of Ashiya et al (5,947,925).

With regard to claim 8, Stevens teaches the invention of claim 1 as discussed above but fails to explicitly teach that the second polymer segment comprises a acetal resin/polyurethane blend. Ashiya et al teaches the second polymer segment comprises a acetal resin/polyurethane blend (column 6, lines 40-61, polyoxymethylene is an acetal resin). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use a polyurethane/polyoxymethylene blend as taught by Ashiya et al in the process taught by Stevens. The motivation to do so would have been to form a

covering sheath from a flexible material with an appropriate rigidity and an appropriate breaking strength (column 6, lines 40-44).

Conclusion

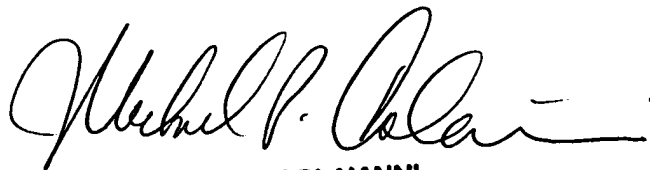
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Beck whose telephone number is 571-272-2942. The examiner can normally be reached on Monday - Friday, 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 517-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DTB
February 7, 2005

DTB



**MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER**